

What is claimed is:

1. A method for determining mutation load which comprises identifying a somatic cell that contains accumulated levels of p53, amplifying DNA of the p53 gene from such cell and determining the frequency or nature of mutations in the amplified DNA.

2. The method of claim 1, in which the somatic cell that is identified also contains altered levels of a protein selected from the group consisting of PCNA and other proteins that are regulated by p53.

3. The method of claim 2, wherein the protein is PCNA.

4. The method of claim 2, wherein the protein is mdm2 or vEGF.

5. The method of claim 1, in which the somatic cell is identified by immunohistochemical staining for p53.

6. The method of claim 2, in which the somatic cell is identified by immunohistochemical staining for p53 and a protein selected from the group consisting of PCNA and other proteins that are regulated by p53.

7. The method of claim 1 or 2, in which the amplification is conducted in the presence of mouse DNA or bovine serum albumin or both.

8. The method of claim 1 or 2, wherein the DNA that is amplified is from exons 5 to 9 of the p53 gene.

9. The method of claim 1 or 2, wherein the DNA that is amplified is at least 1 kb in size.

10. The method of claim 1 or 2, wherein the DNA that is amplified is at least 2 kb in size.

11. The method of claim 1 or 2, in which the amplification is conducted in the presence of mouse DNA having an average size of at least about 20 kb.

12. The method of claim 1 or 2, in which the method is performed on a single somatic cell which is obtained by microdissection from a paraffin-embedded tissue section.

13. The method of claim 12, in which the tissue section is fixed with ethanol.

14. The method of claim 12 in which the tissue section is subjected to steam heating in the presence of EDTA to facilitate unmasking of antigen sites.

15. The method of claim 1 or 2, in which the amplification step utilizes two different DNA polymerases.

16. The method of claim 15, in which the two DNA polymerases are Platinum Taq DNA polymerase High Fidelity (Taq/GB-D) and Platinum Taq DNA polymerase.

17. The method of claim 11, in which amplification comprises use of primers of the sequence GCCGTCTTCCAGTTGCTTTATCTGTTCCT (SEQ. ID. NO. 1) with either CCTGATGGCAAATGCCCAATTGCAGGTAA (SEQ. ID. NO. 2) or GTCAAGTAGCATCTGTATCAGGCAAAGTCATAG (SEQ. ID. NO. 3).

18. The method of claim 17, which further comprises use of primers of the sequence GCCGTCTTCCAGTTGCTTTATCTGTTCCT (SEQ. ID. NO. 1) and CCTGATGGCAAATGCCCAATTGCAGGTAA (SEQ. ID. NO. 2).

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19. The method of claim 17, which further comprises use of primers of the sequence GCCGTCTTCCAGTTGCTTTATCTGTTCACT (SEQ. ID. NO. 1) and GTCAAGTAGCATCTGTATCAGGCAAAGTCATAG (SEQ. ID. NO. 3).

20. The method of claim 12, in which the paraffin-embedded tissue section is prepared from a sample that originated from a patient that is at risk for developing a cancerous condition.

21. The method of claim 12, in which the paraffin-embedded tissue section is prepared from a sample that originated from a patient that is currently receiving treatment for a present cancer condition.

22. The method of claim 21, in the treatment is radiation treatment.

23. The method of claim 21, in the treatment is cytotoxic drug treatment.

24. The method of claim 21, in the treatment is gene therapy treatment.

25. The method of claim 1 or 2, in which the frequency or nature of mutations is determined by sequence analysis which utilizes one or more of TGCCCTGACTTTCAACTCTGTCTC (SEQ. ID. NO. 5), AGGGTCCCCAGGCCTCTGAT (SEQ. ID. NO. 6), GGCCACTGACAACCACCCTTAA (SEQ. ID. NO. 7), AGGTCTCCCAAGGCGCACT (SEQ. ID. NO. 8), GGGGCACAGCAGGCCAGTGT (SEQ. ID. NO. 9), GGAGAGACCGGCGCACAGA (SEQ. ID. NO. 10), or CGGCATTTTGAGTGTTAGACTGGA (SEQ. ID. NO. 11) as primers.

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